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BRH

Procedures to Minimize Diagnostic X-Ray Exposure of the Human Embryo and Fetus

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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radiation recommendation series

Procedures to Minimize Diagnostic X-Ray Exposure of the Human Embryo and Fetus

Division of Training and Medical Applications

BRH
bureau of radiological health

WHO Collaborating Centers for:
- Standardization of Protection Against Nonionizing Radiations
- Training and General Tasks in Radiation Medicine
- Nuclear Medicine

August 1981

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20857

I

FOREWORD

The Bureau of Radiological Health develops and carries out a national program to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiations and to ensure the safe, efficacious use of such radiations. The Bureau publishes the results of its work in scientific journals and in its own technical reports.

These reports provide a mechanism for disseminating results of Bureau and contractor projects. They are distributed to Federal, State, and local governments; industry; hospitals; the medical profession; educators; researchers; libraries; professional and trade organizations; the press; and others. The reports are sold by the Government Printing Office and/or the National Technical Information Service.

The Bureau also makes its technical reports available to the World Health Organization. Under a memorandum of agreement between WHO and the Department of Health and Human Services, three WHO Collaborating Centers have been established within the Bureau of Radiological Health, FDA:

WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations;

WHO Collaborating Center for Training and General Tasks in Radiation Medicine; and

WHO Collaborating Center for Nuclear Medicine.

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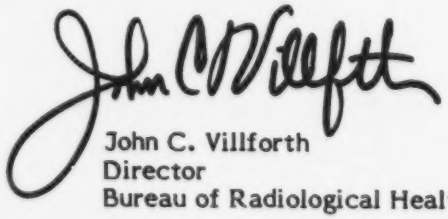

John C. Villforth
Director
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PREFACE

One important aspect of the Bureau of Radiological Health's program to optimize the use of x radiation in the healing arts is the development of recommendations for individual practitioners and health facility personnel regarding ways to minimize radiation exposure of their patients while maximizing its beneficial use. The recommendations published here are intended for the attending physician, the radiologist, the technologist, and the patient delineating their respective roles in optimizing the x-ray exposure of pregnant or potentially pregnant women. These recommendations emphasize the necessity for attending physicians to determine whether or not their patients might be pregnant and to use this information in deciding on the need for an x-ray examination. The recommendations also stress the need to reduce x-ray exposure throughout gestation, and suggest ways in which this can be accomplished.

X-ray exposure of the developing embryo and fetus has been a matter of concern for many years. Several national and international organizations have developed guidelines or policy statements on the subject. The BRH recommendations are expansions of the conceptual foundations provided by these other organizations, and they clarify the ways in which medical radiation exposure can be minimized without compromising the medical care of the mother.

On December 15, 1975, the Food and Drug Administration published a notice in the FEDERAL REGISTER, announcing its intent to develop recommendations on medical radiation exposure of women of childbearing age. Approximately 80 letters of comment and additional requests for information were received in response to the FEDERAL REGISTER notice. The comments were generally supportive of the Agency's intent to develop recommendations. Subsequently, the Bureau of Radiological Health published a Technical Overview, which included an analysis of the current recommendations regarding medical radiation exposure of pregnant or potentially pregnant women, a review of the scientific data relating to the subject, and suggestions for alternative approaches to the management of women of childbearing potential. Copies of the Technical Overview were sent to all organizations, institutions, and individuals who were thought to have an interest in the subject.

Based upon the scientific literature, comments received in response to the FEDERAL REGISTER notice and the Technical Overview, discussions with interested persons, and collaboration with major interested professional and scientific organizations, the Bureau of Radiological Health published proposed recommendations for medical radiation exposure of women of childbearing potential in the FEDERAL REGISTER of November 20, 1979. The many useful comments that were received in response to the proposed recommendations were incorporated into the final recommendations which appear in this report. These recommendations are based on the principle that unnecessary or unproductive medical radiation exposure should be avoided or reduced to the extent possible, while preserving and improving the anticipated benefits of radiological diagnostic information. As with all medical applications of ionizing radiation, the physician's decision to obtain a diagnostic x-ray examination of a pregnant or potentially pregnant patient should be based on the judgment that the medical

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information obtained is likely to be important for appropriate patient management. The examination should be performed with the least amount of radiation necessary to provide the desired imaging information. Under these circumstances, the patient and physician can feel confident that the medical benefit will outweigh possible radiation risks.

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CONTENTS

	Page
Foreword	ii
Preface	iii
Acknowledgments	iv
Introduction	1
Recommendations Regarding Diagnostic X-Ray Exposure of Women of Childbearing Potential	2
Biological Risks to the Embryo and Fetus from Ionizing Radiation	4
Clinical Recommendations About the Use of Ionizing Radiation in Pregnancy: Historical Development	10
Elective Scheduling Systems	17
Basic Principles and Assumptions for the Clinical Management of Pregnant and Potentially Pregnant Patients	22
A Clinical Approach for the Management of Pregnant and Potentially Pregnant Patients	24
Summary	27
References	28

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PROCEDURES TO MINIMIZE DIAGNOSTIC X-RAY EXPOSURE OF THE HUMAN EMBRYO AND FETUS

INTRODUCTION

Exposure to radiation has been associated with a wide variety of adverse effects in the human embryo and fetus, some of which may occur as a result of diagnostic x-ray procedures. The Bureau of Radiological Health (BRH) of the Food and Drug Administration, and clinical and scientific organizations such as the American College of Radiology (ACR) (1), the American College of Obstetricians and Gynecologists (ACOG) (2), and the National Council on Radiation Protection and Measurements (NCRP) (3), as well as other organizations and individuals, have expressed their concerns on the issue of protection of the human embryo and fetus from the effects that might arise from diagnostic x-ray exposure. BRH discussed with the ACR, ACOG, and NCRP the development of their statements or recommendations in a mutual effort to develop new approaches to the management of pregnant and potentially pregnant women being considered for abdominal area x-ray examinations. Previous guidance on the subject, generally referred to as the "Ten Day Rule" and "Fourteen Day Rule," or "Elective Scheduling," is considered by a number of scientists and clinicians to be inadequate or incomplete, and this has stimulated these organizations' more recent efforts. A discussion of the inadequacies of elective scheduling is contained in this report.

Although there are some differences between the BRH recommendations and those of the ACR, ACOG, and NCRP, the basic principles are similar. The BRH recommendations are presented in the same spirit as those of the other organizations, reflecting the assessments and points of view of scientific and clinical participants. They focus particular attention on three important aspects of the issue:

(1) they emphasize that each patient's case should be handled individually (i.e., no single rule is applicable to all patients);

(2) they discuss procedures that are applicable throughout pregnancy, not just during the first month; and

(3) they emphasize the responsibilities of all parties concerned: the attending physician, the radiologist, x-ray facility personnel, and the patient.

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RECOMMENDATIONS REGARDING DIAGNOSTIC X-RAY
EXPOSURE OF WOMEN OF CHILDBEARING POTENTIAL

RECOMMENDATION 1. The attending physician should inquire into the patient's pregnancy status when considering a nonemergency x-ray examination that would place the uterus of a woman of childbearing potential in or adjacent to the direct x-ray beam.

RECOMMENDATION 2. X-ray consultation forms containing information on the patient's pregnancy status should be used to heighten the attending physician's awareness of the need to determine the pregnancy status of a patient prior to requesting an abdominal area x-ray procedure. In the absence of a notification by the attending physician, the x-ray personnel are encouraged to inquire into the pregnancy status of the patient prior to conducting a nonemergency abdominal area examination. If the patient responds that she is or may be pregnant, such personnel are encouraged to notify the radiologist. The responsible radiologist, in turn, is encouraged to consider this information and, if necessary, consult with the attending physician on further actions or changes that may be indicated.

RECOMMENDATION 3. The attending physician should be aware of the logical alternatives available regarding referring pregnant or potentially pregnant patients for abdominal area examinations. Based upon the individual patient's needs, and in consultation, if necessary, with the radiologist, the attending physician may choose to:

i. Request the full abdominal area x-ray examination regardless of pregnancy status when the patient's medical condition dictates immediate need;

ii. Request a limited examination when the diagnostic objectives permit the radiologist to modify the examination by using fewer or more restricted views for a woman who is or may be pregnant;

iii. In the case of a known pregnancy, assess the possibility of deferring the examination until the pregnancy is concluded;

iv. In the case of a possible but unconfirmed pregnancy, defer an examination that is not immediately needed until pregnancy is ruled out. (Although the necessary conditions for its applicability are believed to occur only rarely, this option is presented as a logical alternative course of action. This option may be appropriate for those abdominal area examinations not related to the patient's current illness, or for those needed to obtain baseline or interval information about a known disease. This course of action, sometimes referred to as "elective scheduling," involves scheduling nonemergency abdominal area x-ray examinations during the early part of the menstrual cycle, usually the first 10 to 14 days, to minimize the possibility of irradiating a newly fertilized egg. The examinations suitable for this approach are those few that could safely be postponed until the pregnancy is concluded if the woman subsequently were found to be pregnant.); or

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v. Cancel the examination once aware that the patient is or may be pregnant.

RECOMMENDATION 4. A patient who is or thinks she might be pregnant should alert her attending physician as well as x-ray facility personnel before the performance of an x-ray examination. Also, medical personnel should inform their patients about the importance of volunteering this information.

As used here, the following definitions apply:

1. "Abdominal area examination" means an examination in which the uterus is in or adjacent to the direct x-ray beam (e.g., x-ray examinations of the hip, pelvis, lower abdomen, lower back, and so forth).

2. "Attending physician" means the physician who assumes primary responsibility for the patient's care or who requests an x-ray examination or consultation.

3. "Nonemergency x-ray examination" means an x-ray examination not required for the immediate management of an acute medical or surgical condition.

4. "Radiologist" means specifically a physician who specializes in the practice of radiology, but is used here in a more general sense to include any practitioner who performs or interprets x-ray examinations as a normal component of his or her practice.

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BIOLOGICAL RISKS TO THE EMBRYO AND FETUS FROM IONIZING RADIATION

BACKGROUND

Excellent coverage of the biological basis for this topic is available in the general scientific literature and in "Effects of Ionizing Radiation on the Developing Embryo and Fetus: A Review" (4). Consequently, only a very brief summary is presented in this report for the convenience of the reader.

Experimental studies with animals and human epidemiological studies and case reports have indicated that x-ray exposure represents a hazard to the unborn child. The magnitude and kinds of possible effects depend upon the amounts and types of ionizing radiation received and the stage of fetal development when exposure occurs.

The first trimester of human pregnancy, especially the first 2 weeks after conception, carries the highest risk of abortion induced by radiation. Other somatic effects have been reported as well. The second through sixth weeks following conception are probably the most critical with respect to production of observable anomalies in the unborn child (5-8). Radiation exposure of the fetus during all stages of pregnancy has been associated with an increased incidence of leukemia and other childhood cancers (9-13). There is, however, some suggestion that the carcinogenic effect is greatest for exposure during the first trimester (9). During the second and third trimesters, fetal irradiation is associated with effects on growth and development manifested by physiological and behavioral changes, some of which may not become apparent until later in life (5,14,15). Since both the maternal and fetal gonads may be exposed, abdominal irradiation during any stage of pregnancy may also produce effects in the offspring of both individuals.

Thus there is no time during gestation when the developing embryo or fetus can be irradiated without incurring a risk of some biological effect. Each stage of pregnancy has associated with it the risk of certain radiation induced effects. The kind of effect and its probability of occurence varies with the age of the embryo or fetus and the absorbed dose. It may be true that the largest effects from a given dose occur as a result of exposure early in pregnancy, but it does not follow from this that no effects occur as a result of exposure late in pregnancy, as is frequently implied.

To place the biological consequences of ionizing radiation exposure to the developing embryo and fetus in proper context, it is necessary to discuss not only the types of effects but also their occurrence as a function of dose. The magnitude of potential radiation risks to the embryo and fetus are examined in this report. However, estimates of risk, although useful, contain large uncertainties. By their nature, human epidemiological studies usually contain unavoidable complexities. Furthermore, extrapolation of available data from animal studies to humans is tenuous, and there are few reported risk estimates in humans for effects other than cancer. For example, reliable estimates of the incidence in humans of congenital malformations or subtle somatic and genetic effects are unavailable. Nevertheless, some estimates of the magnitudes of radiation risks to embryos and fetuses, based upon presently available data, limited though it may be, are potentially useful for clinicians.

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Using x-ray examination rates from a 1963 national survey (16), Boice and Burnett (17) estimated that in 1970, 805,000 pregnant women in the United States (23 percent of those who were pregnant that year) received x-ray examinations of all types. Thirty-seven percent of these (298,000) were abdominal x rays. Boice and Burnett further estimated (using the 1963 rates), that during the first trimester, abdominal x-ray examinations were performed on nearly 22,000 pregnant women (each woman receiving on the average 1.2 examinations). If it is assumed that these examinations were divided equally throughout the first trimester, then approximately 7,000 fetuses would have been exposed in the first month of pregnancy, the period when an unsuspected pregnancy is most likely. (See Table 1.) These estimates only represent live births and do not include pregnancies terminated because of spontaneous or induced prenatal death. Furthermore, it should be noted that the use of 1963 examination rates may not be a good indication of current practice; however, they are the only national rates currently available.

Table 1. Estimated Number of Fetuses Irradiated During Abdominal X-Ray Examinations

	Number
U.S. 1970 live births	3,500,000
Pregnant women x-rayed	805,000
Fetuses irradiated during abdominal x-ray examinations:	
All trimesters	298,000
First trimester	22,000
Second trimester	15,000
Third trimester	261,000

It is interesting to note that the estimated number of fetuses irradiated during the third trimester is more than seven times the estimated number irradiated earlier in pregnancy. Most of the third trimester x-ray procedures are pelvimetry examinations (16). (Pelvimetry is a radiographic examination used to visualize and measure the dimensions of the maternal pelvis and fetal head prior to childbirth.)

RISK OF TERATOGENIC EFFECTS

The possible teratogenic effects of x-ray exposure in utero can be considered in three categories: (1) gross morphological changes, varying from polydactyly and subtle spinal abnormalities to exencephaly and severe skeletal malformations; (2) severe mental retardation, often with accompanying microcephaly and smaller-than-normal stature; and (3) more subtle functional changes in the central nervous system, including alterations in neurological function or behavior.

With the exception of a few individual case studies in humans, almost all of the available evidence for gross morphological effects as a result of prenatal irradiation is derived from animal experiments. It has been demonstrated that the dose range most likely to produce these effects is on the order of 25-400 rads, delivered in the early stages of organogenesis (6-8, 18-24). It is not yet possible to make a definitive statement as to the probability of doses below 10 rads inducing teratogenic effects. The consensus

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appears to be that although there may be no threshold for the cellular effects produced by intrauterine irradiation, an "effective" threshold may exist for the gross clinical results of this cellular damage. In other words, it may be that a minimum number of critical cells must be damaged or killed in order for observable structural defects to occur.

Adding to the uncertainty is the usual problem in applying animal data to humans. Although certain fundamental qualitative similarities are presumed to exist in the response of human and rodent embryos to radiation, the extrapolation of quantitative results from animals to humans is subject to considerable error. To make matters worse, there is the serious problem of dosimetry. Many of the animal studies use exposure at the skin to measure the amount of radiation received by the subject. Given the large differences in body dimensions between rodents and humans, and the correspondingly large differences in radiation attenuation in tissue, interpreting this animal data for humans becomes all the more subject to error.

It is thus very difficult to draw any firm conclusions from this animal data with respect to the risk of gross congenital malformations in humans as a result of x-ray exposure during pregnancy, except to say that these effects appear extremely unlikely unless the dose received by the embryo were to exceed 25 rads, a level considerably above that generally encountered in diagnostic radiology. This situation contrasts markedly with the known risks from certain other teratogens. For example, the probability of congenital anomalies as a result of rubella during the first month of pregnancy is roughly 50 percent (25) and the tranquilizers meprobamate and chlordiazepoxide, when administered during the first six weeks of gestation, have been estimated to more than quadruple the normal incidence of some anomalies (26).

With respect to gross mental retardation as a result of intrauterine irradiation, the bulk of available information derives from the Japanese atomic bomb survivors. Here, estimated doses above 50 rads were associated with an increased risk of mental retardation, accompanied in many instances by microcephaly and a general diminution in stature.

The Japanese data leave largely unanswered the question of more subtle, functional changes in the central nervous system as a result of prenatal irradiation. This is because the design of the studies necessitated that the investigators screen the exposed children only for "profound" retardation, that is, that they limit their investigations to children who were grossly retarded (27). Thus, there may have been effects on intelligence and behavior less severe than detected by these studies. These effects may have occurred at doses considerably lower than 50 rads, a possibility that can neither be corroborated nor discounted at the present time.

Along the same lines, animal experiments have shown damage to nerve cells at 10 rads (27). Although this did not result in a measurable deficit in function, considering the large differences between the intellectual capacity of rodents and humans and the difficulties in measuring subtle functional effects on the human central nervous system, it is certainly possible--although not provable at present--that doses on the order of 10 rads or less to the human embryo can produce small alterations in intelligence or behavior. Thus, in the light of available human and animal studies, the possibility of functional central nervous system effects must be borne in mind when considering the potential consequences of x-ray examinations during pregnancy.

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CANCER RISK: FIRST MONTH OF PREGNANCY

The risk of childhood cancer may be present following the irradiation of the fetus at any time during pregnancy. It is particularly important, however, to estimate separately the cancer risk due to irradiation during the first month from the risk due to irradiation at other times. We do this primarily for two reasons. First, abdominal irradiation during the first month of pregnancy is frequently performed without the knowledge that the pregnancy has started. It is, in fact, the avoidance of this situation that is the aim of most recommendations or systems for managing the radiation exposure of women of childbearing potential. Second, irradiation of an early and unsuspected embryo appears to cause most concern among both patients and their physicians. This may be, perhaps, because the existence of an embryo or fetus was not considered when the x-ray examination was requested. In some instances, the x-ray examination may have been performed to investigate symptoms which later were discovered to be due to the pregnancy itself (e.g., "morning sickness"), rather than to some disease state.

Unfortunately, data on the risk of childhood cancer following irradiation during the first month of pregnancy are sparse at best. An article by Bithell and Stewart (9) presents perhaps the best estimates of childhood cancer risks. (This article is an updated version of earlier work by Stewart et al.) The authors derive relative risk estimates of childhood cancer up to age 15 as a function of the time of in utero irradiation. There are, however, some significant difficulties with this study, and a few cautionary words are necessary. The total sample size was not large, and, in particular, the number of childhood cancer cases and controls irradiated during the first trimester was quite small, so that there is much uncertainty associated with the risk estimates. Furthermore, no dose information was available for the study. Because most of the irradiations occurred during the 1940's and 1950's, it is probable that the fetal doses were somewhat larger than those that occur with more modern techniques and equipment. There is, in fact, a trend in the data that suggests that the risk decreases with more recent radiation exposures. Thus, the actual cancer risks from irradiation today may be significantly lower than those found by Bithell and Stewart. Nevertheless, these authors do demonstrate an increased risk of childhood cancer due to in utero irradiation, including a somewhat higher risk from irradiation during the first trimester.

Bithell and Stewart were unable to provide relative risk estimates for the first month of pregnancy because none of the controls were irradiated during this period. Although they provide a lower confidence limit of 2.5 for the relative cancer risk, this is not very satisfactory for estimating the actual level of risk for first month in utero irradiation. This "lower limit" is, however, somewhat larger than the relative risk that Bithell and Stewart claim for irradiation at any time during pregnancy. It should, therefore, be safe to say that although the exact level is undetermined, we expect the cancer risk from first month in utero irradiation to be at least as large as (and probably somewhat larger than) the risk from radiation exposure at other times.

CANCER RISK: ALL OF PREGNANCY

Bithell and Stewart do provide reasonably precise risk estimates for induction of cancer during the first 15 years of life as a result of irradiation of the fetus at some time during pregnancy. They estimate the relative risk to be 1.47 with a 95 percent confidence range of 1.34 to 1.62 (9). To use this estimate to calculate present day risks of in utero irradiation, one would have to assume that the fetal doses in the British experience of several

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years ago is comparable to doses that now occur in the United States. This is surely not so, as noted above. To account for the lower doses that occur with more modern techniques and equipment (e.g., the use of high speed films and x-ray intensifying screens for many x-ray examinations), we will assume that present day fetal doses in the U.S. are a factor of two lower. Although this assumption is somewhat arbitrary, it does take into account the trend in the Bithell and Stewart data, as well as the fact that the practice of radiology has improved significantly in the last twenty or thirty years.

Under this assumption, the relative risk of cancer induction can be roughly calculated to be 1.24, with a range of 1.17 - 1.31. Since approximately 298,000 unborn children may be exposed annually to x radiation from abdominal radiography at some time during pregnancy (Table 1), we estimate that prenatal x-ray examinations in any one year could result in approximately 9 extra cases of childhood cancer each year for the next 15 years (range 6-12). The derivation of this estimate is shown in Table 2. Furthermore, if prenatal irradiation rates remain constant for 15 years, an equilibrium condition will be reached such that the estimated number of childhood cancers from irradiation at any time during pregnancy would be approximately 135 cases per year (range 90-180).

Table 2. Derivation of Estimated Annual Incidence of Childhood Cancers Resulting from Abdominal X-Ray Examinations in Pregnant Women Through All of Pregnancy

	Annual rates	Annual no. in U.S.
Fetuses irradiated from abdominal examinations		298,000
Childhood cancer cases among exposed individuals:		
Natural incidence	12.5/100,000 (28)	37
Natural plus induced incidence	15.5/100,000[a] (range 14.6-16.4)	46 (range 43-49)
Net incidence induced by diagnostic x-ray exposure	3.0/100,000 (range 2.1-3.9)	9 (range 6-12)

[a]This rate corresponds to the naturally occurring rate (12.5/100,000) times the relative risk factor 1.24 (range 1.17-1.31) estimated in the text.

Stated in individual terms, the cumulative probability that a child who was irradiated through a prenatal abdominal x-ray examination will develop cancer during the first 15 years of life is about one in 2000. For individuals who receive larger than average doses, the estima ed risk would be somewhat larger. For example, the radiation received by the embryo from a typical abdominal fluoroscopic procedure is considerably greater than that from 2-3

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plain abdominal area radiographs, which were quoted by Bithell and Stewart as the typical examination in their series, and accordingly, the risk estimate may be substantially larger than one in 2000. It should be emphasized that these risk estimates, which are derived from the results of the Oxford Survey of Childhood Cancers, are subject to revision as medical radiation usage changes. The reader should note that, concerning radiation throughout all of pregnancy, Bithell and Stewart stated, "Analysis of the risk by year of birth shows a pattern of steadily declining risk for both solid and haematopoetic tumors; this may be partly attributable to lower radiation doses per film exposed but is also due to the smaller numbers of films used. A consequence may well be that the risk--always of small clinical significance--would become virtually undetectable in future investigations." (9) (Underscore added.)

In addition to an increased risk of childhood cancer, prenatal irradiation during the last two trimesters may be associated with subtle mental, physiological, and genetic changes that are difficult to detect and measure. Also, other environmental stresses and the genetic character of an individual may modify the biological response to radiation. The human embryo and fetus have been shown to be particularly susceptible to a variety of chemicals, drugs, viruses, and other physical agents. One or more of these agents could augment the effects of x rays, thus altering the foregoing risk estimates.

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CLINICAL RECOMMENDATIONS ABOUT THE USE OF IONIZING RADIATION IN PREGNANCY: HISTORICAL DEVELOPMENT

Although clinical concern for the potentially deleterious effects of medical x radiation was expressed in the literature as early as 1901 (29), its teratological potential was not recognized until some time later. From the 1920's through the mid-1950's, ionizing radiation was used to treat a variety of benign diseases, including procedures that delivered therapeutic radiation to the female pelvis (30). During this period, published reports described developmental abnormalities in children who had been heavily irradiated as fetuses (29, 30). Goldstein and Murphy (1929) reported a high incidence of developmental abnormalities (mainly microcephaly and other mental defects) in children irradiated with high doses of ionizing radiation while in utero. They concluded:

> "It is our belief that therapeutic pelvic irradiation during pregnancy is extremely likely to seriously injure the growing embryo, and that such injury may result in the birth of a seriously defective child." (31)

In 1952, William and Liane Russell reported a series of experimental observations on the teratological effects of x radiation, correlating gestational age at exposure with type of effect. Based upon their assessment of the literature and upon their own laboratory findings, they became concerned with the potential for damage from therapeutic and diagnostic radiological procedures on pregnant women. Consequently, they suggested that pelvic irradiation should be restricted to the 2 weeks following menstruation to minimize the chance of irradiating a woman during an unsuspected pregnancy (32). They concluded:

"In view of the observations reported, it is recommended that:

(a) Whenever possible, irradiation involving the uterus in women of childbearing age should be restricted to the two weeks following the last menstrual period, to preclude the possibility of fertilization having taken place. This applies particularly to diagnostic irradiation, even if the doses involved are less than 25 r (sic).

(b) The present practice of avoiding irradiation during a known pregnancy, i.e., during later stages, should not be relaxed.

(c) Whenever possible in non-pelvic irradiation, the conceptus should be shielded." (32)

In 1955, the Russells further explained the reasoning for their concern for the use of ionizing radiation during pregnancy and reiterated their original recommendation

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"Therapeutic irradiation of the pelvic region can involve doses which are high from the point of view of hazard to the embryo: and certain types of diagnostic irradiation, particularly those involving fluoroscopy, may fall into the dose range for which malformations can be produced with relative ease in the mouse.

"We have, therefore, recommended that, whenever possible, pelvic irradiation of women of childbearing age should be restricted to the two weeks following the menses as there is comparatively little chance of an unsuspected pregnancy during that time." (23)

The clinical recommendation made by the Russells to limit pelvic irradiation of women of childbearing age where possible to the 2 weeks following menstruation was echoed by a number of organizations and individuals. The British Adrian Committee Report emphasized the importance of the menstrual history with reference to radiographic examinations of women.

"Special precautions should be adopted in the radiography of pregnant women. Only essential examinations should be carried out during pregnancy.

"A particular danger is the irradiation of the uterus in an early undiagnosed pregnancy; in general medical and surgical practice the possibility of pregnancy should be considered and inquiry made concerning the recent menstrual history of any woman of childbearing age before any abdominal radiological investigations or the use of radioisotopes are instituted." (33)

The International Commission on Radiological Protection (ICRP) published recommendations in 1964 on the use of radiological procedures involving the lower abdomen and pelvis of women of childbearing age. The ICRP recommended limiting the use of radiological examinations that are not essential to the patient's immediate health to the ten-day interval following the onset of menstruation.

"The Commission wishes to call attention to reports of embryonic and foetal sensitivity to ionizing radiation and to emphasize that the possibility of pregnancy must be taken into account by the attending physician when deciding on radiological examinations that involve the lower abdomen and pelvis of women of reproductive age. The Commission also wishes to point out that the ten-day interval following the onset of menstruation is the only time when it is virtually certain that women of such age are not pregnant. Therefore, it is recommended that all radiological examinations of the lower abdomen and pelvis of women of reproductive age, that are not of importance in connection with the immediate illness of the patient, be limited in time to this period when pregnancy is improbable. The examinations that should be delayed to await the onset of the next menstruation are those that could without detriment be delayed till the conclusion of a pregnancy or at least until its latter half." (34)

This recommendation came to be known as "The Ten Day Rule" (35).

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In 1968, the National Council on Radiation Protection (NCRP) published its original recommendations based on a 10-day interval following the onset of menstruation:

> "2.4.3 Protection of the embryo or fetus during radiological examination or treatment of women known to be pregnant should be given special consideration.
>
> "Comment: Ideally, abdominal radiological examination of a woman of childbearing age should be performed during the first few (approximately ten) days following the onset of menses to minimize the possibility of irradiation of an embryo. In practice, medical needs should be the primary factors in deciding the timing of the examination." (36)

In 1970, the ICRP published a report concerning the use of radiographic examinations in pregnancy which contained the following recommendations:

> "(174) The ICRP has for a number of years called attention to the embryonic and foetal sensitivity to ionizing radiation. The possibility of pregnancy must be taken into account by the attending physician when deciding on examinations that involve the lower abdomen and pelvis of women of reproductive capacity. The Commission has pointed out that the ten-day interval following the onset of menstruation is the time when it is most improbable that such women could be pregnant. Therefore, it is recommended that all radiological examination of the lower abdomen and pelvis of women of reproductive capacity that are not of importance in connection with the immediate illness of the patient, be limited in time to this period when pregnancy is improbable. The examinations that it will be appropriate to delay until the onset of the next menstruation are the few that could without detriment be postponed until the conclusion of a pregnancy or at least until its latter half.
>
> "(175) While pelvimetry is sometimes of great value, it should be undertaken only on the rare occasions when this is likely to be so and should never be carried out on a routine basis." (37)

In 1970, the ICRP published a task group report containing additional commentary and recommendations about the use of radiological procedures during pregnancy:

> "Patient protection during pregnancy is particularly important because radiological examinations of the abdominal region of a pregnant woman frequently result in whole body irradiation of the foetus. Such radiation may contribute to the incidence of childhood leukemia and foetal abnormalities. In addition, these examinations may contribute a substantial proportion of the genetically significant dose. Nonradiological methods of examination may be preferable where they can give comparable information. While pelvimetry is sometimes of great value, it should be undertaken only on the rare occasions when this is likely to be so and should certainly not be carried out on a routine basis. In particular, the supero-inferior projection for the pelvic inlet (sometimes called the brim view) is to

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be discouraged, in view of the high doses delivered to the foetus.

"Where radiography is carried out, it is essential to reduce the beam size to the minimum and this may involve the use of specially shaped apertures (Section 4.03). In addition, it is frequently possible to obtain information of diagnostic value from films of low contrast, and this enables higher kV and filtration than usual to be used. High-speed films and screens are advocated." (38)

In 1971 the NCRP revised its original 1968 recommendations and included a 14-day interval instead of the original 10-day recommendation, which came to be known as "The Fourteen Day Rule."

"When radiological procedures are planned on pregnant or potentially pregnant women, special consideration must be given to the relatively high radiosensitivity of the fetus in utero, particularly during the early phases of gestation. It is recommended that radiologic examinations of the abdomen and pelvis which do not contribute to the diagnosis or treatment of such women in relation to their current illness (e.g., low back examinations for employment) be restricted to the first 14 days of the menstrual cycle in the case of potentially pregnant individuals and avoided entirely during known pregnancy. Examinations of other parts of the body may be done at any time provided such examinations are conducted under conditions carefully designed to limit radiation exposure to an amount necessary for an adequate examination. Filtration, collimation of the radiation beam to the anatomical region of interest and careful selection of technical exposure factors can significantly contribute to good radiation practice and the reduction of radiation exposure to all tissue.

"Examinations of the abdomen and pelvis that are deemed useful to patient care may be done at any time without regard for the phase of the menstrual cycle or fetal presence. In each case the final decision to proceed or not to proceed must reside with the attending physician, in consultation with the radiologist when such services are utilized; that is, the attending physician must retain full and complete discretion to decide each case according to his judgment." (39)

In 1972, recommendations published in the British "Code of Practice" offered guidance for radiological protection of the patient during pregnancy.

"73.1 In all women of reproductive capacity the clinician requesting the examination should consider the possibility of an early stage of pregnancy. The date of the last menstrual period should be entered on the request form and it is the responsibility of the clinician requesting the examination to ascertain this. To reduce the likelihood of irradiation of a pregnancy, examinations involving the lower abdomen should, if practicable, be carried out within 10 days following the first day of the menstrual period.

"73.2 Special precautions should be adopted in the radiography of women known to be pregnant. Only absolutely essential examination should be carried out during pregnancy and

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particular care should be taken to minimize irradiation of the fetus.

"73.3 Mass miniature techniques should not be requested for chest examinations of pregnant women. Full-sized films with strict limitation of field size should be used for these examinations." (40)

The Fourteen Day Rule and other measures designed to safeguard the unborn child from unnecessary prenatal irradiation were recommended in a joint 1971 publication by the American College of Radiology, Public Health Service, and American Medical Association.

"(c) PREGNANT WOMEN (AND WOMEN WHO MIGHT BE PREGNANT)
"The concern here is with the unborn child. X-ray procedures that include the uterus of women who are, or might be, pregnant require particular guidelines in selection and timing. Examinations of other parts of the body may be done at any time provided such examinations are conducted under conditions limiting the radiation exposure to the amount necessary for adequate examination.

"In all women of childbearing age who may be pregnant, the period of choice for examinations involving the abdomen and pelvis is the first 14 days after onset of a menstrual period. In the remainder of the menstrual cycle of women who may be pregnant, the physician should consider whether he would still ask for the examination if the woman were known to be pregnant.

"If the physician considers the examination necessary for immediate patient care, it should be conducted in accordance with good technical practice, even if the patient is pregnant. If he considers the examination useful but not necessary for immediate care, he should consider postponing it.

"In the event that an examination is postponed because of the possibility of pregnancy, and the woman does prove to be pregnant, then a new decision is necessary as to whether further postponement is allowable. This situation is responsible for the recommendation that the only examinations which should be considered for postponement are those which could be further postponed until at least the latter half of pregnancy, without seriously compromising the proper medical care of the patient. The reason for such further postponement, if possible, is that the relatively higher radiosensitivity of the fetus is greater during the first trimester as compared to a later trimester of prenatal life.

"(d) A PRACTICAL POLICY OF X-RAY EXAMINATIONS OF PREGANT WOMEN "The need for an x-ray examination of abdomen and pelvis varies in its importance for the patient's benefit, and the physician must apply a broad scale of urgency, not susceptible to precise definition. At one extreme would be the example of a patient thought to be pregnant and who had relatively minor gastrointestinal or urinary tract symptoms of the type that frequently occur during pregnancy. In this case, there probably is not sufficient indication for a gastrointestinal examination or an excretory urogram. If, on

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the other hand, the patient has unexplained hematuria or melena, there would be adequate indication for proceeding with such a study, even in the case of confirmed pregnancy in the first trimester. In such circumstances, the radiologist should be informed of the pregnancy so that, if possible, the examination could be modified to reduce radiation dose to a level even lower than usual.

"If an x-ray examination is performed before the patient's pregnancy is discovered, there is normally little cause for concern. In most procedures, the radiation exposure is so small that the risk of interference with fetal development is negligible. Such radiation exposure alone should not be used as a justification for interruption of the pregnancy. In very unusual circumstances when it is suspected that a diagnostic procedure or combination of procedures may have resulted in an uncommonly large exposure, efforts should be made to determine the fetal dose, and experts should be consulted about the possible hazard." (41)

In addition to the recommendations of the NCRP and the ICRP, other individuals and institutions have expressed their concern for the unnecessary use of ionizing radiation in pregnancy.

For example, the American College of Radiology has also stated that:

"Abdominal radiological examinations that have been requested after full consideration of the clinical status of the patient, including the possibility of pregnancy, need not be postponed or selectively scheduled, except in those infrequent instances where the examination may not be related to the patient's current illness." (1)

The American College of Obstetricians and Gynecologists has stated that:

"1. The use of x-ray examinations should be considered on an individual basis. Concern over harmful effects should not prevent the proper use of radiation exposure when significant diagnostic information can be obtained. Pre-examination consultation with a radiologist may be useful in obtaining optimal information from the x-ray exposure.

"2. There is no measurable advantage to scheduling diagnostic x-ray examinations at any particular time during a normal menstrual cycle.

"3. The degree of risk involved in an x-ray examination if the person is pregnant, or should become pregnant, should be explained to the patient and documented in her record." (2)

Bishop has stated:

"Prior to pelvic radiation of women of childbearing age, the radiologist should ascertain the time of the last normal menstrual period and if there is a remote possiblity of pregnancy. X-ray examinations involving the pelvis should be avoided whenever possible, and in spite of the statistical

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improbabilities, the safest procedure is to restrict pelvic radiation to the 2 weeks following menstruation.

"During pregnancy, roentgen studies of parts of the body other than the pelvis and lower abdomen are probably safe, since no direct rays reach the embryo and scattered rays are minimal. Even so, as an added precaution, the pelvic area should be shielded from accidental direct exposure by use of protective lead material." (42)

Still another view expressed by Jacobsen is that:

"In order to avoid irradiation of the conceptuses of undiagnosed early pregnancies, irradiation should as far as possible be performed only during the first half of the menstrual cycle. Women who are known to be pregnant should only be Roentgenologically examined on very strong clinical indications." (29)

Rugh has stated:

"Radiodiagnosis and radiotherapy are absolutely essential to modern medicine. However, ionizing radiations are so potent and penetrating that the highly radiosensitive human embryo and fetus should be protected against any exposure if at all possible, particularly during the first six weeks after conception. When the mother's health is in jeopardy, she must take priority over the fetus in any decision regarding the use of irradiation." (15)

In summary, a number of organizations and individuals have manifested their concern for protecting embryos from medical radiation exposure by recommending clinical protocols based in principle on the Russells' recommendations.

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ELECTIVE SCHEDULING SYSTEMS

Some hospitals and other clinical facilities have instituted operating protocols based upon either the existing 10-or 14-day rules or modifications of them. These protocols, sometimes called "elective scheduling systems," call for the scheduling of nonemergency abdominal x-ray examinations of women of childbearing age during the first 10 days to 2 weeks of their menstural periods, when pregnancy is unlikely. Sometimes, nonemergency high fetal-dose examinations (barium enemas, lumbar spine, intravenous pyelography, and so forth) are performed during the first 10 days of the menstrual cycle, while lower fetal-dose examinations (upper GI series, thoracic spine, cholecystography, and so forth) are performed immediately, unless the patient is 28 days past her last menstrual period and hence late. In the latter case, the examination is postponed in consultation with the attending physician until the onset of menstruation (43). This section will outline the major characteristics of elective scheduling systems, and discuss their benefits and limitations. In this regard, it is important to point out that patients fall into two classes when using these systems. The smaller group consists of those patients who are actually, but unknowingly, pregnant. The larger group consists of those potentially pregnant women who are, in fact, not pregnant. The former group has embryos that might benefit from efforts to curtail abdominal x-ray exposure of their mothers whereas in the latter group there are no viable embryos to benefit from such efforts. Consequently, analysis of the net public health benefits and limitations of elective scheduling systems must include the health implications not only to the embryos at risk but also to both sets of women patients involved.

Regardless of their differences, systems for scheduling abdominal area x-ray examinations for women of childbearing age generally have in common the following features:

1. Patients are queried to determine the likelihood of their being pregnant. Scheduling of an examination to avoid irradiating an embryo is considered unnecessary (because pregnancy is unlikely or impossible) if any of the following conditions are discovered to exist:

   a. Menstruation has never occurred.

   b. Onset of menstruation occurred less than 10 (or 14) days before the examination is planned.

   c. Menstruation has ceased because of menopause, hysterectomy, or oophorectomy.

   d. Bilateral tubal ligation has been performed.

   e. Birth control pills are taken regularly.

   f. Intra-uterine device has been fitted.

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g. Intercourse has not occurred since the last menstrual period.

h. The patient's mate has been vasectomized or is otherwise infertile.

2. In order to avoid the irradiation of a newly fertilized egg, elective scheduling systems are intended for patients who are not known to be pregnant, but who could be. In other words, these systems are intended for women who are in the post-ovulatory stage but who have not yet missed a menstrual period, i.e., those who could possibly be in the first 2 weeks of pregnancy. (The patient's actual pregnancy status will, of course, not be known to her or her physician.) As practiced at several U.S. medical facilities, the radiology department schedules the woman's abdominal x-ray examination during the time of her next expected menses. Pregnancy is not likely to occur during the menstrual period, so if her menstrual period starts as expected, the examination is performed. If her menstrual period does not start and if her medical condition still warrants the examination, then some alternative measures must be taken.

3. Scheduling systems are appropriate only for elective examinations. If, in the opinion of the attending physician, a patient's symptoms warrant an immediate radiological examination, it is performed immediately. This implies that any radiation damage to a potential embryo is considered to be less likely or less serious than the larger risk of medical harm to the woman if diagnosis and treatment are delayed, and the risk of consequent indirect harm to her child if her health is thus impaired. Each scheduling system depends upon a decision by an attending physician concerning whether or not the patient's symptoms warrant an immediate examination. The criteria applied by each physician in making this decision are in part objective and undoubtedly in part subjective and intuitive.

4. Scheduling systems are appropriate only for abdominal area examinations. Other diagnostic x-ray procedures do not contribute a significant dose to the embryo or fetus, and with the application of appropriate techniques, can be performed at any time during pregnancy without appreciable risk to a developing child.

5. Scheduling systems rely on either the radiology department or the attending physician to screen female patients. In the latter case, the attending physician is usually required to enter the date of the last menstrual period on the x-ray referral slip.

Elective scheduling systems have several limitations. The NCRP and ICRP scheduling recommendations both specify that they are appropriate only for those examinations which, if the patient is found to be pregnant on the scheduled date of the examination, may be postponed to a later period of pregnancy or after delivery without significantly compromising the patient's medical care.

Scheduling recommendations, in effect, require that the attending physician make a personal commitment. That is, the physician must decide when the patient is first seen that, if she is found to be pregnant at the time of her schduled examination, the examination will be postponed until term or at least the latter half of pregnancy. This effectively limits the number of x-ray examinations that are appropriate for elective scheduling, because it is likely

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that in only a relatively few cases could a physician be reasonably sure in advance that the patient's condition will not deteriorate to the extent that the physician will be forced to order the x-ray procedure whether she proves to be pregnant or not.

However, this important commitment is not made and followed in elective scheduling systems as they are practiced in some institutions. Although the ICRP recommendation states that few examinations qualify for postponement to term, medical facilities have generally tended to include all nonemergency abdominal examinations in their elective scheduling protocols. Consequently, women may be scheduled for examinations for which postponement may be medically unjustified. As a result, for those women who are postponed to await the onset of menses, who are later discovered to be pregnant, but whose examination becomes necessary (i.e., no longer "elective"), the examination will be performed during the period of organogenesis, a time when the embryo is most sensitive to congenital malformations. In this case the application of the Russells' recommendation may actually increase the risk they intended it to reduce. It should be re-emphasized that this situation would theoretically not occur if the ICRP or NCRP rules were rigorously followed. These rules state that the only examinations that should be postponed are those few that are not related to the current illness of the patient - those predictably elective examinations that could safely be postponed until term or the latter part of gestation if the woman is, in fact, pregnant.

In those institutions where the NCRP and ICRP recommendations are followed as they were intended, the attending physician's judgment is paramount. In the usual course of events, only the attending physician has all the pertinent clinical facts (symptoms, history, other diagnostic findings, and so forth) to decide whether a contemplated examination meets the strict criteria for elective scheduling and possible postponement.

Elective scheduling is of no direct benefit to those women who are not found to be pregnant after the postponement period, since they were also not pregnant when the physician first saw them, and therefore could have had the examination without delay. In fact, postponement of the x-ray examination for these individuals may have served only to delay their effective medical treatment. Of course, by the very nature of the problem, an attending physician could not have predicted whether a woman patient was actually pregnant or not when the decision to postpone an examination was made. However, the fact that a substantial proportion of women have nothing to gain from elective scheduling and may actually be at some medical risk from the delay, must be considered in the complete public health evaluation of these systems.

Furthermore, certain patients may not return for the scheduled examination, hence endangering their own health. Although it is true that in some cases the need for an x-ray examination may no longer exist by the time the patient is scheduled to receive it, it is not acceptable medical practice to arbitrarily postpone indicated diagnostic tests and appropriate treatment on the chance that some patients may improve without it.

The ICRP and NCRP recommendations and many clinical scheduling systems apply only to women who have menstrual flows of normal intensity occurring regularly every 28 days, and whose ovulation occurs at about mid-cycle and can thus be calculated with some certainty. The use of the 10- or 14-day rules to determine a "safe period" is not applicable in women with irregular cycles or women who menstruate more or less frequently than monthly. These women have about a 10-percent chance of ovulating during the first 10 days of their cycles and about a 50 percent chance during the first 14 days (17). Elective scheduling systems also rely on obtaining a reliable menstrual history from the

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patient, which, because of its personal nature or other factors, may be difficult to obtain accurately.

The ICRP, in advising that abdominal examinations be postponed at least until the latter half of pregnancy, has implicitly accepted the radiogenic risks that might accrue then, in trade for the risks in the first month of pregnancy. Following the rule does not eliminate all risk to the fetus, unless the examination is postponed until term. A judgment about acceptable risks might be more properly the province of the physician and the patient.

Scheduling systems relate only to the potentially pregnant patient and provide no advice on managing the patient who is known to be pregnant. Yet these systems are sometimes erroneously considered a comprehensive solution to the problem of medical radiation exposure throughout gestation. We estimate that, in 1970, 276,000 fetuses were irradiated in the U.S. during the second and third trimesters, a time when the pregnancy is undoubtedly known. In the same year, only 22,000 fetuses were irradiated during the first trimester. Even if all the first trimester x-ray examinations met criteria for postponement, only 7 percent (22,000/298,000) of all irradiated fetuses could have been affected. It is clear that elective scheduling systems are not a comprehensive approach to all medical radiation exposure during pregnancy.

Elective scheduling systems do, however, provide certain benefits. First, they make physicians aware that x-ray exposure of the fetus may be harmful, and this awareness probably causes some physicians to rethink the need for an examination of a woman they suspect of being pregnant. Further, they may stimulate physicians to take more care in inquiring about the patient's pregnancy status. Finally, they may eliminate some unneeded examinations because some patients will no longer be ill following the postponement period. However, this latter benefit will be counterweighed by those situations where postponement leads to a worsening of a medical condition.

HYPOTHETICAL CASES

The following hypothetical cases illustrate some advantages and disadvantages of scheduling women of childbearing age according to the "Ten Day Rule."

Case 1: A woman who is beyond the 10-day interval since the onset of menses must be scheduled for an abdominal x-ray examination. She is given an appointment for a time during the 10-day interval following the onset of her next menses. She has her next menses and receives her x-ray examination. She obviously was either not pregnant at any time since her last menses or, if she was pregnant, has unknowingly had a spontaneous abortion. She could have been scheduled at any time during that period without danger to a viable embryo. Consequently, her postponement benefited no one. It is also possible that she suffered some aggravation of her medical condition because of a delay in diagnosis and treatment of her condition caused by postponing the x-ray examination. It is also possible that the delay was inconsequential to her health.

Case 2: A patient who is beyond the 10-day interval must be scheduled for an abdominal x-ray examination during the 10-day interval following the onset of her next menses. Her menses do not begin on schedule and she believes she is pregnant. Assuming that fertilization has occurred on the fourteenth day after the onset of her last menses, the embryo is now about 2 weeks postconception and entering the period of early organogenesis. Her physician decides he still needs the examination despite her early pregnancy. (The examination has turned out to be one that the physician, contrary to ICRP and

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NCRP recommendations, could not safely postpone until term.) The fetus is now irradiated during the period of organogenesis, when the risk of congenital malformations from x radiation is greatest. In this case, postponement placed the fetus at greater risk of congenital malformations than if the examination had been done earlier. (Of course, had it been performed earlier, another type of risk would have been involved, a small increase in the probability of embryonic death. There is no period during gestation when the embryo or fetus is completely free of any risks because of x-ray exposure.)

Case 3: Another patient who was scheduled for an abdominal x-ray examination during her next menses recovers from her illness in the meantime. Her physician then decides that the x-ray procedure is not needed. In this case, postponement resulted in benefit to the patient by eliminating the risk and cost of an x-ray procedure.

Case 4: This patient is found to be pregnant following the postponement to await the onset of menses. Her physician decides to postpone the examination until after her child is born. Since the examination may be postponed for such a long period of time, it could be questioned whether the examination is needed at all. There is also a possibility that postponement may delay an important diagnosis and thus adversely affect the mother's (and perhaps indirectly the child's) health. On the other hand, postponement until term does eliminate all exposure of the unborn child.

Clearly, the only women who will menstruate after they are postponed are those who were not pregnant originally (or who lost the embryo shortly after conception), and who therefore never had a viable embryo at risk. Except for abortions, spontaneous or induced, those who were pregnant stay pregnant. For these women, the physician faces the crucial decision of whether or not to proceed with the examination. As mentioned earlier, the embryo may have progressed to the period of major organogenesis, a particularly radiosensitive period in its development, when its risk of congenital malformation may be highest. Additionally, the mother's medical condition may have worsened.

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BASIC PRINCIPLES AND ASSUMPTIONS FOR THE CLINICAL MANAGEMENT OF PREGNANT AND POTENTIALLY PREGNANT PATIENTS

Before considering an alternative course of action to existing scheduling systems, there are several underlying principles and assumptions that must be recapitulated. Any logical and biologically justified approach must take these into account.

1. Review and analysis of the pertinent literature supports the assumption that the developing embryo and fetus is subject to various radiation risks. The kind and degree of risks vary depending upon the precise embryonic age at which the radiation is delivered, a number of biological and environmental variables, and a number of physical factors such as the quantity, type, energy, and spatial and time distributions of the radiation involved.

2. It is prudent to assume that no amount of medical x-ray exposure to the embryo and fetus is completely without effect at any time during pregnancy. During the earlier part of pregnancy the embryo may be somewhat more susceptible to radiogenic risks than at later stages.

3. Primary care physicians have the dual responsibility to provide appropriate medical care for their patients and to be cognizant of radiological risks and to take them into account in their patient care decisions. This is one of the underlying assumptions on which both the ICRP and NCRP recommendations are based. This is especially important when the physician has to consider both the health benefits to the patient from the x-ray examination and the radiation risk to the embryo or fetus if the patient proves to be pregnant.

It is an interesting anecdotal observation that some mothers and some physicians respond differently to the issue of radiological risks to the embryo, depending upon whether an abdominal x-ray procedure was given prior to knowledge about a patient's pregnancy, or whether it was given in full knowledge of the pregnancy. In either case, if all other variables are the same, (e.g., gestational age, technical conduct of the procedure, and so forth), the risks are the same. Also, reduction of avoidable risks is important from a public health point of view, but physicians and patients should realize that the individual risks are small, and their reactions should be tempered accordingly. Nonetheless, the collective impact of individual efforts to reduce unproductive radiation exposure is the only way in which public health progress can be accomplished.

4. Expert organizations and governmental agencies can play an important role through the development and dissemination of scientific information that can aid the physician's decision making, but only the physician can competently make the final decision about the necessity for or timing of an x-ray examination. The competing concerns of protecting mother and embryo or fetus from radiogenic risks, and providing the needed medical care, must be properly balanced by the patient's physician and not by

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remote parties, in order that one concern is not given inordinate weight at the expense of the other.

The system recommended here for radiological management of pregnant or possibly pregnant women, takes into account all of the above principles and assumptions.

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A CLINICAL APPROACH FOR THE MANAGEMENT OF PREGNANT AND POTENTIALLY PREGNANT PATIENTS

Given the foregoing principles and assumptions, the following alternative system to elective scheduling is recommended. It emphasizes the collective responsibilities of attending physician, patient, radiologist and other x-ray department personnel. This alternative system can effectively fulfill the primary goal of the 10- or 14-day rules, which is to avoid the unintentional irradiation of a newly fertilized egg, and can, at the same time, minimize several major drawbacks inherent in elective scheduling.

ATTENDING PHYSICIANS

The attending physician is the most important person with respect to the irradiation of a pregnant or potentially pregnant patient. By an x-ray request, the attending physician initiates the process that culminates in the x-ray exposure of the patient and possibly also an unborn child. As will be discussed below, radiological personnel can take measures to keep the exposure to a necessary minimum, but the attending physician must decide whether or not it is needed at all. This decision must start with the assumption that the physician is requesting an x-ray examination only after due consideration of its necessity in the treatment of the patient. (Note: A major effort to develop x-ray referral criteria has been initiated in a joint effort by BRH, the American College of Radiology and other medical organizations. Such referral criteria, to be announced elsewhere as they are developed, may aid physicians in deciding about the necessity of specific x-ray procedures under certain circumstances of patient signs, symptoms, and history.)

The physician should ascertain the likelihood that the patient is or may be pregnant, unless the situation is of such an emergency nature that the information would be irrelevant. This is identical to the procedure described under "Elective Scheduling Systems." One method that has been suggested and used in some institutions to assure that attending physicians invariably ascertain the pregnancy status of the patient, when appropriate, is the annotated referral slip. On the referral request itself, space is provided for the attending physician to indicate: whether the patient is, is probably not, or may be pregnant; whether or not the examination should be performed irrespective of pregnancy status; whether the physician would like to consult the radiology department about the possibility of modifying the requested examination; or whether the examination should be postponed for a time. In some institutions, a space is provided on the referral slip for the attending physician to note the date of the patient's last menstrual period. The referral slip can be a permanent record of the consideration of pregnancy if it is appropriately filed and can be retrieved. Whether or not the annotated referral slip can be an effective tool in assuring that attending physicians ascertain the possibility of pregnancy depends upon how vigorously the radiology department insists that attending physicians complete all parts of the referral slip and sign it.

When the attending physician either suspects the possibility of pregnancy in the patient being considered for an abdominal area x-ray examination, or knows she is pregnant, the second step is to make one of the following choices:

BEST DOCUMENT AVAILABLE

i. Request the full abdominal area x-ray examination regardless of pregnancy status when the patient's medical condition indicates immediate need. This option is a logical alternative when the patient's medical circumstances dictate an immediate need for the examination, regardless of her pregnancy status.

ii. Request a limited examination when the diagnostic objectives permit the radiologist to modify the examination by using fewer or more restricted views for a woman who is or may be pregnant. Under certain circumstances, an abdominal area x-ray examination involving fewer exposures or more restricted views than routine may be used by the radiologist to provide the necessary clinical information with less x-ray exposure. Whether a limited examination is in the best interests of the mother's and child's health must be decided on an individual basis. The attending physician is, therefore, encouraged to consult with the radiologist on this matter.

iii. In the case of a known pregnancy, assess the possibility of deferring the examination until the pregnancy is concluded. As discussed earlier, the embryo or fetus is at risk of different types of radiation induced injury throughout gestation. However, there is evidence that the carcinogenic effect is greatest when irradiation occurs during the first trimester. This option recognizes that there are some abdominal area examinations that, although necessary, may be deferred for a time long enough into pregnancy so that the risk to the fetus or embryo is appreciably reduced. In some cases, the examination might even be deferred until the pregnancy is concluded, eliminating all risk to the embryo or fetus.

iv. In the case of a possible but unconfirmed pregnancy, defer an examination that is not immediately needed until pregnancy is ruled out. (Although the necessary conditions for its applicability are believed to occur only rarely, this option is presented as a logical alternative course of action. This option may be appropriate for those abdominal area examinations not related to the patient's current illness, or for those needed to obtain baseline or interval information about a known disease. This course of action, sometimes referred to as "elective scheduling," involves scheduling nonemergency abdominal area x-ray examinations during the early part of the menstrual cycle, usually the first 10 to 14 days, to minimize the possibility of irradiating a newly fertilized egg. The examinations suitable for this approach are those few that could safely be postponed until the pregnancy is concluded if the woman subsequently were found to be pregnant, e.g., those examinations associated with chronic conditions.)

v. Cancel the examination once aware that the patient is or may be pregnant. The potential health benefit to be gained from a contemplated examination can vary and if the attending physician is convinced that the x-ray procedure is medically necessary, the patient's pregnancy or possible pregnancy should not deter the examination. However, if there is less certainty of the necessity for the examination, the attending physician may decide not to proceed with the examination.

PATIENTS, RADIOLOGISTS, AND X-RAY PERSONNEL

Participation in avoiding medical x-ray exposure of the human embryo and fetus involves more persons than the attending physician. The x-ray examination process involves three main stages: the determination that a patient will undergo the examination, the conduct of the x-ray examination, and the

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interpretation of the examination results. Both the attending physician and the patient have key roles to perform during the first stage.

The patient's most important task is to inform the attending physician if she suspects or knows that she is pregnant. She should also inform her physician about any previous x-ray examinations she has had. This examination history may be beneficial in eliminating the need for some examinations, if a recent examination can provide the information needed. Finally, knowing that she is scheduled to receive an x-ray examination of the abdominal area, the patient should postpone a planned pregnancy until after the examination.

The person, usually a technologist, who performs the x-ray examination is instrumental in determining the dose received by the patient and hence the embryo or fetus. It is beyond the scope of this report to discuss in detail all the factors that should be considered by the operator in performing an x-ray examination. However, a few points should be stressed. Before performing an abdominal area examination on a woman of childbearing age, x-ray personnel should ask her whether or not she could be pregnant. In those situations where the patient is or may be pregnant, x-ray personnel should notify the physician in charge, usually a radiologist, before performing the examination.

The x-ray exposure of <u>any patient</u> should be kept to a necessary minimum in the performance of an x-ray examination by use of proper technique factors, proper film-screen combinations, collimation to the area of interest, and the other well-known techniques involved in quality radiologic technology. A facility quality assurance program can be important in reducing the need for repeat examinations and hence in avoiding unnecessary radiation exposure. These procedures are expecially important when a pregnant woman is given an x-ray examination, because a developing embryo is being exposed as well as a patient.

Although not directly involved with this stage of the examination, the attending physician can influence the conduct of the examination by consulting with the radiologist about the patient's pregnancy and clinical history. The radiologist, based upon the attending physician's needs, can then advise on the feasibility of modifying the examination to reduce fetal exposure and determine the procedures to be followed by the machine operator during the conduct of the examination. Based upon the particular examination and clinical needs, the radiologist may also provide guidance concerning the use of fetal shielding.

Various ultrasound procedures are replacing or supplementing certain x-ray examinations. The attending physician should realize that it is not yet known whether diagnostic ultrasound conveys biological risks, and he/she should be vigilant for such information appearing in the medical literature. However, the physician may wish to consult with a radiologist about the advantages and limitations of these procedures where certain required information might be obtained by ultrasound techniques.

The radiologist also has the responsibility for the final stage of the examination process, that of interpreting the results. It is also incumbent upon the radiologist to provide feedback to the attending physician and x-ray personnel to improve their practices, if necessary. For example, should the radiologist observe an unsuspected fetus in the field of view, both the attending physician and x-ray personnel should be informed to increase their awareness of the need to ask female patients about their pregnancy status prior to the ordering and performance of abdominal x-ray examinations. Through this feedback process, the radiologist can influence the future actions of both attending physicians and x-ray technologists.

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SUMMARY

The attending physician's judgment is the critical key to any efforts to reduce unnecessary medical x-ray exposure to the fetus, since it is the decision of the attending physician that places an individual into the x-ray examination process. There is no satisfactory way of circumventing the physician's responsibility without causing undesirable medical consequences, nor can the rules imposed by remote parties be expected to alleviate more risk of undesirable consequences than they may cause. The attending physician's judgment has always been important, even where elective scheduling has been practiced. The promulgation of elective scheduling recommendations and their practice in certain institutions may have tended to obscure the fact that attending physicians must choose between several alternative courses of action, no one of which is universally appropriate for all pregnant and possibly pregnant patients.

The attending physician cannot claim to have considered all pertinent aspects of the patient's condition when ordering an examination (or, for that matter, a drug), unless some effort has been made to inquire whether the patient is or may be pregnant. Nor can the physician adequately weigh the merits of the other options without this information.

Once the attending physician has made a decision to proceed with an examination, the patient, the radiologist, and x-ray personnel all play vital roles in keeping the subsequent exposure and risk to a minimum. Although redundancies appear in the system, they serve a useful purpose in insuring that the process is effective.

When considering abdominal x-ray examinations for a female patient of childbearing age, the attending physician should take positive steps to ascertain and document whether the patient may be pregnant. He should also possess a realistic understanding of the nature and degree of the risks to the developing embryo from diagnostic radiological procedures. With this information, the physician can decide upon the course of action that is best for the patient and her child. Proper conduct of the examination, feedback of information to the attending physician and x-ray personnel, and actions the patient can take are also important in improving the total patient management process. These steps collectively appear to be a more suitable response to the complexities involved in the radiological care of pregnant and potentially pregnant patients than elective scheduling routines.

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